510(k) Summary of Safety and Effectiveness

FEB - 1 2010

iU22 Diagnostic Ultrasound System

This summary of safety and effectiveness information is submitted in accordance with 21CFR §807.92

1. **Submitter's name, address, telephone number, contact person.**

Philips Ultrasound, Inc.
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

Contact person: Nancy Burke, Regulatory Affairs Specialist
Email: Nancy.Burke@philips.com
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Date prepared: November 3, 2009

2. **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/usual name: Diagnostic ultrasound system and transducers
Proprietary name: iU22 Ultrasound System

These devices are classified as follows:

Classification Name	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90IYO
Diagnostic Ultrasound Transducer	892.1570	90ITX

As stated in 21 CFR, parts 892.1550, 892.1560 and 892.1570, each of these generic types of devices have been classified as Class II.

3. **Substantially Equivalent Devices**

Philips Ultrasound believes that the iU22 Ultrasound System is substantially equivalent to the following currently marketed devices:

Product	510(k)
Philips iU22	K042540
Siemens Acuson S2000	K072786
Philips QLAB	K021966, K023877

4. Device Description and Technical Comparison to Predicate Devices

The subject of this 510(k) notification, the iU22 ultrasound system and transducer(s), function in a manner identical to all diagnostic ultrasound systems and transducers. The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The Doppler functions of system process the Doppler shift frequencies from the echoes of moving targets such as blood to detect and graphically display the Doppler shifts of these tissues as flow.

The iU22 system gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used by competent healthcare professionals to make a diagnosis.

5. Intended Use

The iU22 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging, Harmonics (Tissue and Contrast) and Elastography modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Ophthalmic
Fetal
Intra-operative
Abdominal
Laparoscopic
Pediatric
Small Organ
Adult and Neonatal Cephalic
Trans-rectal
Trans-vaginal
Musculoskeletal
Urology
Cardiac (Adult, Pediatric, Trans-esophageal)
Fetal Echo
Peripheral Vessel

The clinical environments where the iU22 3.7 system can be used include point-of-care areas in offices, clinical and hospital settings for diagnosis of patients.

6. Conclusion

iU22 Ultrasound System and transducers is substantially equivalent in safety and effectiveness to the predicate devices identified above:

- The systems are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- The systems have the same gray-scale and Doppler capabilities.
- The systems have acoustic output levels below the Track 3 FDA limits.
- The systems are manufactured under equivalent quality systems.
- The systems are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- The systems are designed and manufactured to the same electrical and physical safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB - 1 2010

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K093563
Trade/Device Name: iU22 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 12, 2010
Received: January 13, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the iU22 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

L12-5

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): _____

Device Name: iU22 Diagnostic Ultrasound System

Indications for Use:

The iU22 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging, Harmonics (Tissue and Contrast) and Elastography modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Ophthalmic
Fetal
Intra-operative
Abdominal
Laparoscopic
Pediatric
Small Organ
Adult and Neonatal Cephalic
Trans-rectal
Trans-vaginal
Musculoskeletal
Urology
Cardiac (Adult, Pediatric, Trans-esophageal)
Fetal Echo
Peripheral Vessel

The clinical environments where the iU22 3.7 system can be used include point-of-care areas in offices, clinical and hospital settings for diagnosis of patients.

Prescription Use ___XX_____ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K093563

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No:
System: **iU22 Ultrasound System**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	P	P	P		P	Notes 1,3	Notes, 5,6,8,10,12,13
Fetal Imaging & Other	Fetal (includes Echo)	P	P	P		P	Notes 1,2,3	Notes, 5,6,7,8,10,11,12,13
	Abdominal (includes urology)	P	P	P		P	Notes 1,2,3	Notes, 5,6,7,8,9,10,11,12,13
	Intra-operative (Abdominal, cardiac, spine, Vascular)	P	P	P	E*	P	Notes 1,2,3,4	Notes 5,6,8,10,12,13
	Intra-operative (Neuro.)	P	P	P		P	Notes 1, 3	Notes 3,5,6,10,12,13
	Laparoscopic	P	P	P		P	Notes 1, 3	Notes 8,10,12,13
	Pediatric	P	P	P	E*	P	Notes 1,2, 3	Notes 5,6,8,9,10,12, 13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Notes 1,2, 3	Notes 5,6,8,9,10,11,12,13,15
	Neonatal Cephalic	P	P	P		P	Notes 1,3	Notes 5,8,10,12,13
	Adult Cephalic	P	P	P	P	P	Notes 1,3,4	Notes 10, 13
	Trans-rectal	P	P	P		P	Notes 1,3	Notes 5,6,10,11,12, 13
	Trans-vaginal	P	P	P		P	Notes 1,2,3	Notes 5,6,7,10,11,12,13
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Notes 1,2,3	Notes 5,6,8,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Notes 1,2,3	Notes 5,6,8,10,12,13
	Intra-luminal							
	Other: Urology	P	P	P		P	Notes 1,3	Notes 5,6,10,12
Cardiac	Cardiac Adult	P	P	P	P	P	Notes 1,2,3,4	Notes 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Notes 1,2,3,4	Notes 10,11,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Notes 1,2,3,4	Notes 10,11,12,13
	Other (Fetal Echo)	P	P	P	P	P	Notes 1,2,3,4	Notes 5,10,12,13
Peripheral Vessel	Peripheral vessel	P	P	P		P	Notes 1,2,3,4	Notes 2,3,5,6,8,9,10,12,13
	Cerebral Vascular	P	P	P		P	Notes 1, 2, 3	Notes 5,6,8,9,10,12,13

N= new indication; P= previously cleared (K042540); E= added under Appendix E (*9/21/2005)

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: EFOV including Amplitude Doppler
Note 2: Combined modes include: B+M+Color	Note 10: Harmonic Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: Contrast Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: 3D Imaging
Note 5: SonoCT	Note 13: XRES
Note 6: Imaging for guidance of biopsy	Note 14: TDI
Note 7: Infertility monitoring of follicle development	Note 15: Elastography

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K093563

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No:
System: **iU22 Ultrasound System**
Transducer: **L12-5**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Notes 1, 3	Notes 5,6,8,10,12,13
	Abdominal	P	P	P		P	Notes 1, 3	Notes 5,6,8,10,12,13
	Intra-operative (cardiac)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Notes 1, 3	Notes 5,6,8,10,12,13
	Small Organ (Breast, thyroid, testicle)	P	P	P		P	Notes 1, 3	Notes 5,6,8,10,11,12,13,15
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Notes 1, 2, 3	Notes 5,6,8,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Notes 1, 2, 3	Notes 5,6,8,10,12,13
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Fetal Echo							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Notes 1, 2, 3	Notes 5,6,8,9,10,12,13
	Cerebral Vascular	P	P	P		P	Notes 1, 2, 3	Notes 5,6,8,9,10,12,13

N= new indication; P= previously cleared (K030455), E= Added under appendix E.

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: EFOV including Amplitude Doppler
Note 2: Combined modes include: B+M+Color	Note 10: Harmonic Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: Contrast Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: 3D Imaging
Note 5: SonoCT	Note 13: XRES
Note 6: Imaging for guidance of biopsy	Note 14: TDI
Note 7: Infertility monitoring of follicle development	Note 15: Elastography

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K093563